

CLAIMS

1. A biocompatible implant, comprising:
 - A) a biological molecule; and
 - B) a support.
- 5 2. A biocompatible implant according to claim 1, wherein the biological molecule includes a protein.
- 10 3. A biocompatible implant according to claim 1, wherein the biological molecule includes a cellular physiologically active substance.
- 15 4. A biocompatible implant according to claim 1, wherein the biological molecule includes a cell adhesion molecule.
5. A biocompatible implant according to claim 1, wherein the biological molecule includes an extracellular matrix.
- 20 6. A biocompatible implant according to claim 1, wherein the biological molecule includes a cellular adhesive protein.
7. A biocompatible implant according to claim 1, wherein the biological molecule includes an integrin.
- 25 8. A biocompatible implant according to claim 1, wherein the biological molecule is selected from the group consisting of collagen and laminin.
- 30 9. A biocompatible implant according to claim 1, wherein the biological molecule includes a fiber forming collagen or basement membrane collagen.

10. A biocompatible implant according to claim 1, wherein the biological molecule includes a fiber forming collagen and basement membrane collagen.

5 11 A biocompatible implant according to claim 1, wherein the biological molecule includes type I collagen or type IV collagen.

10 12. A biocompatible implant according to claim 1, wherein the biological molecule includes collagen and cytokine.

13. A biocompatible implant according to claim 1, wherein the support is in the form of a membrane.

15 14. A biocompatible implant according to claim 1, wherein the support is in the form of a tube.

15. A biocompatible implant according to claim 1, wherein the support is in the form of a valve.

20 16. A biocompatible implant according to claim 1, wherein the support includes biodegradable polymer.

25 17. A biocompatible implant according to claim 1, wherein the support includes at least one component selected from the group consisting of poly(glycolic acid) (PGA), poly(L-lactic acid) (PLA) and polycaprolactum (PCLA).

30 18. A biocompatible implant according to claim 1, wherein the support includes PGLA having a glycolic acid-to-lactic acid ratio of from about 90 : about 10 to about 80 : about 20.

19. A biocompatible implant according to claim 1, wherein the support includes a cell adhesion molecule.
- 5 20. A biocompatible implant according to claim 1, wherein the support includes a protein.
- 21 A biocompatible implant according to claim 1, wherein the support is in the form of a mesh and a sponge.
- 10 22. A biocompatible implant according to claim 1, wherein the support has a thickness of at least about 0.2 mm to about 1.0 mm.
- 15 23. A biocompatible implant according to claim 1, wherein the support has a strength of at least about 20 N.
24. A biocompatible implant according to claim 1, wherein the support has a strength of at least about 50 N.
- 20 25. A biocompatible implant according to claim 1, wherein the support is coated with the biological molecule.
26. A biocompatible implant according to claim 1, wherein the support has a gap and the gap is filled with the biological molecule.
- 25 30 27. A biocompatible implant according to claim 1, wherein the biological molecule and the support include a crosslinking molecule, and the crosslinking molecules are crosslinked between the support and the biological molecule.
28. A biocompatible implant according to claim 1, wherein the support includes the same material as the biological

molecule.

29. A biocompatible implant according to claim 1, wherein
a cell is attached to the biocompatible implant.

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30. A biocompatible implant according to claim 1, for use
in implantation into a body.

10 31 A biocompatible implant according to claim 30, wherein
a site of the body into which the biological implant is
implanted is selected from the group consisting of cardiac
valve, blood vessel, pericardium, cardiac septum,
intracardiac conduit, extracardiac conduit, duramater, skin,
bone, soft tissue and trachea.

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32. A biocompatible implant according to claim 1, which is
sterilized.

20 33. A biocompatible implant according to claim 1, further
comprising an immunosuppressant.

34. A biocompatible implant according to claim 1, further
comprising an additional medicament component.

25 35. A biocompatible implant according to claim 30, wherein
the biocompatible implant is derived from an organism
undergoing the implantation.

30 36. A medicament according to claim 1, comprising a
biocompatible implant according to claim 1.

37. A medical kit, comprising:

 a biocompatible implant according to claim 1; and

instructions describing usage of the implant,
wherein the instructions describe that the implant
is administered to a predetermined site.

5 38. A medical kit according to claim 37, wherein the
predetermined site is selected from the group consisting
of vascular endothelium, vascular smooth muscle, elastic
fiber, skeletal muscle, cardiac muscle, osteoblast, neuron
and collagen fiber.

10 39. A medical kit according to claim 37, wherein the
instructions describe that the biocompatible implant is
implanted in such a manner that at least a part of an organ
or tissue to be subjected to implantation is left *in situ*.

15 40. A method for treating an injured site of a body, comprising
the step of:

 A) implanting a biocompatible implant to a part or
whole of the injured site,

20 wherein the biocompatible implant comprises:

- A-1) a biological molecule; and
- A-2) a support.

25 41 A method according to claim 40, wherein in the implanting
step, the biocompatible implant is implanted in such a manner
that at least a part of an organ or tissue to which the injured
site belongs is left *in situ*.

30 42. A method according to claim 40, further comprising
administering a cellular physiologically active substance.

43. A method according to claim 42, wherein the cellular
physiologically active substance is selected from the group

consisting of a granulocyte macrophage colony stimulating factor (GM-CSF), a macrophage colony stimulating factor (M-CSF), a granulocyte colony stimulating factors (G-CSF), a multi-CSF (IL-3), a leukemia inhibiting factor (LIF), a 5 c-kit ligand (SCF), an immunoglobulin family member, CD2, CD4, CD8, CD44, collagen, elastin, proteoglycan, glycosaminoglycan, fibronectin, laminin, syndecan, aggrecan, an integrin family member, integrin α chain, integrin β chain, fibronectin, laminin, vitronectin, 10 selectin, cadherin, ICM1, ICAM2, VCAM1, platelet derived growth factor (PDGF), epidermal growth factor (EGF), fibroblast growth factor (FGF), hepatocyte growth factor (HGF) and vascular endothelial growth factor (VEGF), and polypeptides and peptides related thereto..

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44. A method according to claim 40, further comprising performing a treatment for suppressing an immune reaction.

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45. A method for reinforcing an organ or tissue in a body, comprising the step of:

A) implanting a biocompatible implant to a part or whole of the organ or tissue,

wherein the biocompatible implant comprises:

A-1) a biological molecule; and

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A-2) a support.

46. A method for producing or regenerating an organ or tissue, comprising the steps of:

A) implanting a biocompatible implant to a part or whole of the organ or tissue within an organism containing the organ or tissue,

wherein the biocompatible implant comprises:

A-1) a biological molecule; and

A-2) a support; and

B) culturing the organ or tissue within the organism.

5 47) Use of a biocompatible implant according to claim 1 for treatment of an injured site within a body.

48) Use of a biocompatible implant according to claim 1 for reinforcement of an organ or tissue within a body.

10 49) Use of a biocompatible implant according to claim 1 for production of a medicament for treatment of an injured site within a body.

15 50) Use of a biocompatible implant according to claim 1 for production of a medicament for reinforcement of an organ or tissue within a body.

51 A biocompatible tissue support, comprising:

20 A) a first layer having a rough surface; and
B) a second layer having a strength which allows the second layer to resist *in vivo* impact,
wherein the first layer is attached to the second layer via at least one point.

25 52. A support according to claim 51, wherein the first layer is a knit.

30 53. A support according to claim 51, wherein the second layer is a woven.

54. A support according to claim 51, wherein the rough surface has sufficient space for accommodating cells.

55. A support according to claim 51, wherein the attachment is carried out by melting a biological absorbable macromolecule.

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56. A support according to claim 51, wherein the second layer has substantially no permeability to air.

10 57. A support according to claim 51, wherein the strength of the support is at least 100 N.

58. A support according to claim 51, wherein the air permeability of the support is no more than 10ml/cm²/sec.

15 59. A support according to claim 51, wherein the first layer includes a biodegradable material.

20 60. A support according to claim 51, wherein the first layer includes at least one component selected from the group consisting of poly(glycolic acid) (PGA), poly(L-lactic acid) (PLA), and polycaprolactum (PCLA) and a copolymer thereof.

25 61. A support according to claim 51, wherein the first layer includes PGLA having a glycolic acid-to-lactic acid ratio of from about 90 : about 10 to about 80 : about 20.

62. A support according to claim 51, wherein the first layer includes poly(glycolic acid).

30 63. A support according to claim 51, wherein the second layer includes a biodegradable material.

64. A support according to claim 51, wherein the second layer

includes at least one component selected from the group consisting of poly(glycolic acid) (PGA), poly(L-lactic acid)(PLA) and polycaprolactum (PCLA), and a copolymer thereof.

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65. A support according to claim 51, wherein the second layer includes PGLA having a glycolic acid-to-lactic acid ratio of from about 90 : about 10 to about 80 : about 20.

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66. A support according to claim 51, wherein the second layer includes poly(L-lactic acid).

67. A support according to claim 51, wherein the second layer is a woven and the first layer is a knit.

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68. A support according to claim 51, wherein the second layer is a woven of poly(L-lactic acid) and the first layer is a knit of poly(glycolic acid).

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69. A support according to claim 51, wherein the attachment is carried out by:

C) an intermediate layer for attaching the first layer with the second layer.

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70. A support according to claim 69, wherein the intermediate layer is made of a synthetic biological absorbable polymer.

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71. A support according to claim 69, wherein the intermediate layer includes a homopolymer containing a single monomer selected from the group consisting of lactic acid (lactid), glycolide and ε-caprolactam or a copolymer containing two or more monomers therefrom.

72. A support according to claim 69, wherein the intermediate layer includes a material having a melting point lower than a melting point of the second layer and a melting point of the first layer.

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73. A support according to claim 51, wherein the first layer comprises a plurality of knit layers.

10 74. A support according to claim 51, wherein the first layer comprises a plurality of knit layers.

75. A support according to claim 51, wherein a biological molecule is provided on the first layer.

15 76. A support according to claim 75, wherein the biological molecule is an extracellular matrix.

20 77. A support according to claim 75, wherein the biological molecule includes an extracellular matrix selected from the group consisting of collagen and laminin.

78. A support according to claim 75, wherein the biological molecule is contained in a microsponge and the microsponge is provided on the first layer.

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79. A support according to claim 75, wherein the biological molecule is crosslinked with the support.

30 80. A medical device comprising a support according to claim 51.

81 A medical device according to claim 80, further comprising a cell.

82. A medicament according to claim 80, for use in implantation into a body.

5 83. A medicament according to claim 80, wherein a site of
the body into which the biological implant is implanted is
selected from the group consisting of cardiac valve, blood
vessel, pericardium, cardiac septum, intracardiac conduit,
extracardiac conduit, dura mater, skin, bone, soft tissue
10 and trachea.

84. A medicament according to claim 80, wherein the biocompatible implant is derived from an organism undergoing the implantation.

15 85. A method for producing a biocompatible tissue support, wherein the biocompatible tissue support comprises:

A) a first layer having a rough surface; and
B) a second layer having a strength which allows the
second layer to resist *in vivo* impact,

wherein the first layer is attached to the second layer via at least one point, and

the method comprises the step of:

attaching the first layer with the second
25 layer.

tissue support further comprises:
G) an intermediate layer for attaching the first layer

30 with the second layer.

the attaching step comprises:

a) providing the intermediate layer between the first layer and the second layer;

b) providing the first layer, the second layer and the intermediate layer under conditions that the first layer and the second layer are not melted and the intermediate layer is melted; and

5 c) the intermediate layer is provided under conditions that the intermediate layer is solidified, while retaining desired shapes of the first layer, the second layer and the intermediate layer.

10 87. A method according to claim 86, wherein the melting point of the intermediate layer is lower than both the melting points of the first layer and the second layer and a difference between the melting points is utilized.

15 88. A method according to claim 86, wherein the second layer is a woven of poly(L-lactic acid) and the first layer is a kit of poly(glycolic acid), and the intermediate layer includes a homopolymer containing a single monomer selected from the group consisting of lactic acid (lactid), glycolide 20 and ε-caprolactam or a copolymer containing two or more monomers therefrom.

25 89. A method according to claim 88, wherein the temperature is higher than the melting point of the intermediate layer and is lower than the melting points of the first layer and the second layer.

30 90. A method according to claim 86, wherein the support further comprises a biological molecule and the method further comprises the step of:

attaching the biological molecule to the first layer.

91 A method according to claim 90, wherein the attaching

step comprises crosslinking treatment.

92. A method according to claim 90, wherein the biological molecule is collagen, and the attaching step comprises
5 collagen crosslinking treatment.

93. A method according to claim 86, wherein the intermediate layer is produced by casting a film material onto a glass plate, followed by air drying, to form a film.

10 94. A method according to claim 86, wherein the step b) comprises exerting a pressure of at least about 0.1 g/cm² onto the support.

15 95. A method according to claim 86, wherein the step b) comprises exerting a pressure of at least about 0.5 g/cm² onto the support.

20 96. A method for treating an injured site of a body, comprising the step of:

A) implanting a biocompatible tissue support to a part or whole of the injured site,
wherein the biocompatible tissue support comprises:
A-1) a first layer having a rough surface; and
25 A-2) a second layer having a strength which allows the second layer to resist *in vivo* impact,
wherein the first layer is attached to the second layer via at least one point.

30 97. A method for reinforcing an organ or tissue within a body, comprising the step of:

A) implanting a biocompatible tissue support to a part or whole of the injured site,

wherein the biocompatible tissue support comprises:

A-1) a first layer having a rough surface; and

A-2) a second layer having a strength which allows the second layer to resist *in vivo* impact,

5 wherein the first layer is attached to the second layer via at least one point.

98. A method for producing or regenerating an organ or tissue, comprising the steps of:

10 A) implanting a biocompatible tissue support to a part or whole of the organ or tissue within an organism containing the organ or tissue,

wherein the biocompatible tissue support comprises:

A-1) a first layer having a rough surface; and

15 A-2) a second layer having a strength which allows the second layer to resist *in vivo* impact,

wherein the first layer is attached to the second layer via at least one point; and

20 B) culturing the organ or tissue in the organism.

99. Use of a biocompatible tissue support for treatment of an injured site within a body, wherein

the biocompatible tissue support comprises:

25 A-1) a first layer having a rough surface; and

A-2) a second layer having a strength which allows the second layer to resist *in vivo* impact,

wherein the first layer is attached to the second layer via at least one point.

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100. Use of a biocompatible tissue support for reinforcement of an organ or tissue within a body, wherein

the biocompatible tissue support comprises:

A-1) a first layer having a rough surface; and
A-2) a second layer having a strength which allows
the second layer to resist *in vivo* impact,
wherein the first layer is attached to the second
5 layer via at least one point.

101. Use of a biocompatible tissue support for production
of a medicament for treatment of an injured site within a
body, wherein
10 the biocompatible tissue support comprises:
A-1) a first layer having a rough surface; and
A-2) a second layer having a strength which allows
the second layer to resist *in vivo* impact,
wherein the first layer is attached to the second
15 layer via at least one point.

102. Use of a biocompatible tissue support for production
of a medicament for reinforcement of an organ or tissue within
a body, wherein
20 the biocompatible tissue support comprises:
A-1) a first layer having a rough surface; and
A-2) a second layer having a strength which allows
the second layer to resist *in vivo* impact,
wherein the first layer is attached to the second
25 layer via at least one point.